UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP.,

Plaintiff,

v.

Case No. 2:21-cv-10312

Hon. F. Kay Behm

BLUEWILLOW BIOLOGICS, INC.; ROBIN ROE 1 through 10, gender neutral fictitious names; and ABC CORPORATION 1 through 10 (fictitious names).

Defendants.

DEFENDANT/COUNTER-PLAINTIFF BLUEWILLOW BIOLOGICS, INC.'S OPPOSITION TO PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT DECLARING THAT U.S. PATENT NO. 8,163,802 IS VALID

Pursuant to Local Rule 7.1(c) of the United States District Court for the Eastern District of Michigan, Defendant/Counter-Plaintiff BlueWillow Biologics, Inc. ("BlueWillow"), by and through its undersigned counsel, Foley & Lardner LLP, hereby responds to Plaintiff/Counter-Defendant Trutek Corp.'s ("Trutek") Motion for Partial Summary Judgment Declaring that U.S. Patent No. 8,163,802 is Valid.

For the reasons stated in the accompanying Brief in Support, the Court should deny Trutek's Motion.

Dated: June 5, 2023

Respectfully submitted,

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DEFENDANT/COUNTER-PLAINTIFF BLUEWILLOW BIOLOGICS, INC.'S BRIEF IN SUPPORT OF OPPOSITION TO PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT DECLARING THAT U.S. PATENT NO. 8,163,802 IS VALID

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STATEMENT OF ISSUE PRESENTED

1. Whether the Court should declare that U.S. Patent No. 8,163,802 is valid.

   BlueWillow's answer: **No**.

   Trutek's answer: **Yes**.

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I. INTRODUCTION

The main premise of Plaintiff's Motion For Partial Summary Judgment Declaring that U.S. Patent No. 8,163,802 is Valid (ECF 62) is that U.S. Patent No. 8,163,802 ("the '802 patent") is presumed to be valid and Defendant BlueWillow has not demonstrated invalidity of the '802 patent by clear and convincing evidence because it applied incorrect legal standards. BlueWillow intends to prove at trial and/or through its own motion for summary judgment (ECF 59) that the '802 patent is invalid under one or more grounds, including lack of patentable subject matter, lack of credible utility, failure to comply with the written description and enablement requirements, and obviousness or anticipation in view of multiple prior art references. Contrary to Trutek's arguments, each of BlueWillow's invalidity defenses is supported factually (including through its expert, Dr. Amiji) in view of controlling legal authority set by the Supreme Court and the Federal Circuit.

Trutek's Motion is arguably not even a proper motion for summary judgment at all. Not only did Trutek fail to apply the proper standard for demonstrating it is entitled to summary judgment of patent validity, but it also doesn't even credibly point to any instances where it believes there is an absence of clear and convincing evidence on a material fact that is essential to any of BlueWillow's invalidity defenses. Instead, Trutek resorts to unsupported and conclusory attorney argument based on its own misunderstanding of patent law. In doing so, Trutek largely repeats

the same flawed reasoning underlying its Motion to Exclude Testimony of Mansoor M. Amiji, Ph.D. (ECF 61), arguing that Dr. Amiji's opinions are legal in nature, he is a person of "extraordinary" skill, and "misunderstood" the law. Not only are those arguments improper in the summary judgment context, but they should be entirely disregarded for the reasons previously explained by BlueWillow in opposing Trutek's motion to exclude (ECF 73). Trutek has failed to meet its burden demonstrating that the '802 patent should be declared valid on summary judgment and Trutek's Motion (ECF 62) should be denied in its entirety.

II. FACTUAL BACKGROUND

Dr. Amiji is a qualified technical expert in pharmaceutical sciences. He has testified as a technical expert in over eighteen cases in the past four years in front of both federal courts and the Patent Trials and Appeal Board. ECF 59-2, PageID 1717-23. Defendant BlueWillow submitted three expert reports from Dr. Amiji: (1) Opening Expert Report, on technical patent invalidity issues (*id*. at PageID 1712-1825) (**Ex. 1**); (2) Responsive Expert Report to Edward Lemmo's, Alexei Ermakov's, and Shane Burns' Reports on issues related to infringement (*id*. at PageID 1828-52); and (3) Reply Report to Edward Lemmo's and Amirali Haidri's Reports on issues related to invalidity (*id*. at PageID 1855-83).

Plaintiff's expert, Amirali Haidri, submitted one expert report responding to Dr. Amiji's opening report on invalidity issues. Mr. Haidri's report and proposed

expert testimony are the subject of Defendant's Motion to Exclude as containing (1) impermissible legal opinion and argument from a patent attorney and (2) impermissible technical opinions from an expert who lacks the appropriate technical qualifications to testify as a person of ordinary skill in the art. ECF 56.[1]

Another expert for Plaintiff, Dr. Lemmo, submitted one expert report responding to only a limited set of issues related to patent invalidity, including (1) the level of skill of the person of ordinary skill in the art ("POSA"); (2) scope of the '802 patent claims; (3) enablement of a single prior art reference ("Rolf"); and (4) purported commercial success. ECF 62 at 5.

On January 23, 2023, the Court extended the deadline for filing summary judgment motions to March 29, 2023 and extended the page limits for briefs in support of and in opposition to such motions to forty pages. ECF 55. BlueWillow timely filed its Motion for Summary Judgment on March 28, 2023. ECF 59. Trutek

[1] Trutek submitted a declaration from Mr. Haidri in support of its Motion (ECF 62-2), but does not reference that declaration apart from describing Mr. Haidri's purported qualifications (ECF 62 at 4), which BlueWillow disputes. ECF 65. The remainder of the declaration consists of legal argument from a patent attorney.

did not comply with the Court's January 23, 2023 order, filing its Motion for Partial Summary Judgment (ECF 62) on March 30, 2023, one day after the deadline.[2]

III. LEGAL STANDARD

A court can only grant summary judgment "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). A genuine issue of material fact exists if, by viewing the evidence in a light most favorable to the nonmoving party, a reasonable jury could return a verdict for that party. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The moving party always bears initial responsibility for showing the absence of genuine fact whereas the non-movant need only point to an evidentiary dispute created on the record. *See Finish Eng'g Co. v. Zerpa Indus., Inc.*, 806 F.2d 1041, 1044 (Fed. Cir. 1986).

"[A] moving party seeking to have a patent held not invalid at summary judgment must show that the nonmoving party, who bears the burden of proof at trial, failed to produce clear and convincing evidence on an essential element of a defense upon which a reasonable jury could invalidate the patent. In determining

[2] Although Trutek's Motion is dated March 29, 2023, it was not filed until March 30, 2023, as evidenced by the ECF-generated header at the top of its motion. Trutek did not seek leave from the Court for permission to file its Motion out of time.

whether a genuine issue of material fact exists, the court views the evidence in the light most favorable to the nonmoving party and resolves all doubts in its favor." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 962 (Fed. Cir. 2001) (citing *Anderson*, 477 U.S. at 255; *Transmatic, Inc. v. Gulton Indus., Inc.*, 53 F.3d 1270, 1274 (Fed. Cir. 1995)).

"An opinion is not objectionable just because it embraces an ultimate issue." Fed. R. Evid. 704. Courts addressing admissibility of expert testimony on issues of patent invalidity routinely permit properly qualified technical experts to provide opinion testimony on ultimate issues of patent invalidity as long as such testimony is adequately supported by facts. *E.g.*, *Icon Health & Fitness, Inc. v. Strava, Inc.*, 849 F.3d 1034, 1041 (Fed. Cir. 2017); *Formax, Inc. v. Alkar-Rapidpak-MP Equip., Inc.*, No. 11-C-298, 2014 WL 3057116, at *2 (E.D. Wis. July 7, 2014); *Voter Verified, Inc. v. Premier Election Solutions, Inc.*, No. 6:09-cv-1968-Orl-19KRS, 2010 WL 3123129, at *5 (M.D. Fl. Aug. 9, 2010).

IV. ARGUMENT

In order to prevail on summary judgment for validity of the '802 patent, Trutek must show that there is no genuine issue of material fact for each of BlueWillow's invalidity defenses under 35 U.S.C. §§ 101, 102, 103, and 112. *Eli Lilly & Co.*, 251 F.3d at 962. Trutek has failed to meet its burden on summary

judgment, and indeed, identifies almost no issues of *fact* in its Motion[3] (or even the applicable standard that applies to its Motion). Instead, Trutek repeats the same flawed rationale that Dr. Amiji is not qualified to provide opinion testimony on issues of patent invalidity and incorrectly argues that Dr. Amiji did not apply the proper legal standards.

Disagreement with the legal standards considered by an expert, however, is not an issue of fact appropriate for resolution on summary judgment or a proper basis to entirely disregard their testimony. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986) ("Credibility determinations, the weighing of evidence, and the drawing of legitimate inferences from the facts are jury instructions, not those of a judge, whether he is ruling on a motion for summary judgment of for a directed verdict."); *InTouch Techs, Inc. v. VGO Commc'ns, Inc.*, 751 F.3d 1327, 1348-49

[3] One "fact" that Trutek identifies – "the NasalGuard products sold in the United States all have Trutek's patent numbers (including that of the '802 Patent) clearly marked on their packaging – is not even a "fact" that is relevant to patent invalidity. ECF 62 at 1-2. The issue of patent marking is relevant only to Trutek's ability to recover pre-suit damages and the lack of evidence on this issue is addressed in BlueWillow's Motion for Summary Judgment. ECF 59 at 28-31. Exhibit 3 to Trutek's Motion is a copy of the packaging from a single NasalGuard product marked with the '802 patent and falls well short of demonstrating that Trutek's marking efforts were "substantially consistent and continuous" and do not address whether Trutek's licensees complied with the marking requirements of 35 U.S.C. § 287. *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1111 (Fed. Cir. 1996); *Arctic Cat Inc. v. Bombardier Recreational Prod. Inc.*, 876 F.3d 1350, 1366 (Fed. Cir. 2017).

(Fed. Cir. 2014) (considering the legal standards used by an expert when reviewing the factual findings reached by the jury).

Rather, it is Trutek's understanding of the relevant patent law that is flawed, and Dr. Amiji's testimony is properly grounded in technical analysis and facts in view of the correct legal standards. Trutek has failed to meet its burden to show "that there is no genuine issue as to any material fact" directed to any of BlueWillow's invalidity defenses or that it is entitled to judgment of patent validity as a matter of law. Fed. R. Civ. P. 56(c).

A. Dr. Amiji's Invalidity Opinions Are Appropriate

As a preliminary matter, Dr. Amiji's opinions on patent invalidity as provided through his expert reports are proper. None of Trutek's arguments – Dr. Amiji's opinions are legal in nature, he is not a lawyer and was informed of the law by counsel, he relied on prior art references provided by counsel, and purportedly misinterpreted the patent statute (ECF 62 at 3-4) – carry any weight and Trutek has not cited any authority demonstrating otherwise.

Technical experts are not the source of legal standards, correct or otherwise. *See Plexxikon Inc. v. Novartis Pharms. Corp.*, No. 17-cv-04405-HSG, 2020 WL 2301213, at *2 (N.D. Cal. May 8, 2020); *Formax*, 2014 WL 3057116, at *3; *Niazi Licensing Corp. v. St. Jude Medical S.C., Inc.*, No. 17-cv-5096 (WMW/BRT), 2020 WL 5512507, at *5 (D. Minn. Sept. 14, 2020). An expert, however, is permitted to

state the law he applied when reaching his conclusions; such a statement is relevant to determine if the testimony is credible and puts the testimony in context. *See Voter Verified*, 2010 WL 3123129, *aff'd*, 698 F.3d 1374, 1384 and n.6 (Fed. Cir. 2012); *Medicines Co. v. Mylan, Inc.*, No. 11-cv-1285, 2014 WL 1257943, at *2-3 (N.D. Ill. Mar. 27, 2014). To the extent Trutek has any disagreement with the standards Dr. Amiji applied, those should be addressed during cross examination. *See Marine Travelift Inc. v. ASCOM SpA*, No. 14-C-443, 2015 WL 9008254, at *1 (E.D. Wis. Dec. 15, 2015).

Additionally, experts are permitted to offer their opinion on ultimate issues of law. *See Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294 (Fed. Cir. 1985); *see also* Fed. R. Evid. 704(a) ("An opinion is not objectionable just because it embraces an ultimate issue."). Specifically for prior art based issues of patent invalidity, "[a] technical expert's role under these circumstances is to explain why earlier technology anticipates or renders obvious the claims of a patent; in doing so, the expert is not rendering a legal opinion but merely a factual-expert opinion based on his own expertise and experience." *Formax*, 2014 WL 3057116, at *2; *see also Icon Health*, 849 F.3d at 1041; *Voter Verified*, 2010 WL 3123129, at *5. Likewise, Courts routinely rely on technical expert testimony for issues under 35 U.S.C. §§ 101, 112 and a POSA's understanding. *See, e.g., In re '318 Patent Infringement Litigation*, 583 F.3d 1317, 1326-27 (Fed. Cir. 2009); *Ziarno v.*

American Nat'l Red Cross, 55 F. App'x 553, 555-556 (Fed. Cir. 2003); *Bone Care Intern., LLC v. Pentech Pharms., Inc.*, 862 F. Supp. 2d 790, 809-811 (N.D. Ill. 2012); *Infernal Tech., LLC v. Sony Interactive Entertainment LLC*, No. 2:19-cv-00248-JRG, 2021 WL 405813, at *3 (E.D. Tex. Feb. 3, 2021).

Nor are technical experts required to be patent law experts to act as an expert witness on issues of patent invalidity. *Endress + Hauser, Inc. v. Hawk Measurement Sys. Pty. Ltd.*, 122 F.3d 1040, 1042 (Fed. Cir. 1997) ("It is of course nonsense to contend that only lawyers or patent lawyers can be expert witnesses in a patent suit."). Because technical experts are not required to be lawyers, they do not need to supply the legal standards relevant to their analysis. Instead of identifying legal standards himself, Dr. Amiji properly relied on the information provided by counsel. *See Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd.*, 807 F.3d 1283, 1303 (Fed. Cir. 2015). Indeed, counsel are not precluded "from providing assistance to experts in preparing [the] expert reports, and . . . this assistance may be needed." *WNS Holdings, LLC v. United Parcel Service, Inc.*, No. 08-cv-275-BBC, 2009 WL 2136961, at *4 (W.D. Wis. July 14, 2009) (citing Fed. R. Civ. P. 26(a)(2)(B) advisory committee note (1993)) (finding that even though counsel provided expert the legal standards, it did not follow that the expert's opinions were merely parroting attorney argument.), *aff'd*, 368 F. App'x 144 (Fed. Cir. 2010).

Trutek's complaint that counsel provided Dr. Amiji with patent references is disingenuous and also lacks any merit. As an initial matter, Trutek cites no case law that even suggests this is not permitted. Trutek also ignores several salient facts, including that many of the prior art references Dr. Amiji relies on were the subject of an expert declaration he prepared in a prior petition for *inter partes review* of the '802 patent on behalf of Matrixx before he was even retained by BlueWillow. ECF 61-3 (Amiji Tr.) at 62:1-3. With respect to the Baker prior art, Dr. Amiji testified he was personally aware of that art before his involvement in this case based on his professional relationship with Dr. Baker and the University of Michigan. *Id*. at 63:1-15. Regardless of the source of the prior art, Dr. Amiji also credibly testified that "the analysis is all mine and the opinions are all mine." *Id*. at 61:9-19.

B. Dr. Amiji Is Qualified to Provide Invalidity Testimony From the Perspective of a POSA

Trutek again repeats the same meritless argument that Dr. Amiji cannot testify about issues from the perspective of a POSA because he has "extraordinary" skill. ECF 62 at 6-8. The POSA is a theoretical construct who is presumed to be aware of all pertinent prior art. *See Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986). The POSA is a hypothetical person and not descriptive of a particular individual. *Endress*, 122 F.3d at 1042. Moreover, the "actual inventor's skill is not determinative." *Custom Accessories*, 807 F.2d at 962.

In order to offer testimony from the perspective of a POSA, an expert must have *at least* ordinary skill in the art. *Endress*, 122 F.3d at 1042; *Kyocera Senco Indus. Tools, Inc. v. International Trade Comm'n*, 22 F.4th 1369, 1377 (Fed. Cir. 2022) ("[I]t would be improper to require an expert witness to possess ordinary skill in the art and *nothing more*. If that were the case, 'a person of exceptional skill in the art would be disqualified from testifying as an expert because [he is] not ordinary enough.'"). Dr. Amiji possesses *at least* the qualifications of a POSA, as defined by the Court in this matter.[4] Plaintiff is clearly not arguing that Dr. Amiji is less qualified than a POSA.

Nor is it reasonable that Dr. Amiji's opinions should be ignored because the Court disagreed with his definition of the POSA. Indeed, Dr. Amiji addressed the Court's adopted definition in his reply report and claim construction declaration, noting how the lower standard impacts his §112 analysis and concluding that despite the lower standard, it did not impact any of his opinions provided in his opening report. ECF 38-3 at ¶¶ 21-23, 39-41; ECF 59-2 at PageID.1855, 1862-65 (¶¶ 20-23, 26). Trutek's citation to *Custom Accessories* for the proposition that "[i]ncorrect determination of the qualifications of a PHOSITA has resulted in reversible error"

[4] Notably, in its Motion, Trutek again concedes that the POSA is a "pharmaceutical formulator" (ECF 62 at 21), despite taking an inconsistent position in opposing BlueWillow's motion to exclude the testimony of Mr. Haidri (ECF 75 at 2-4).

(ECF 62 at 7) does not instruct otherwise. Notably, the Federal Circuit in *Custom Accessories* was considering the district court's application of *Graham v. John Deere Co.*, 383 U.S. 1 (1966), not the expert's application of the POSA standard. *Custom Accessories*, 807 F.2d at 963 ("In the present case, we do not reverse or vacate solely because of a failure to make the level of skill finding. We merely consider the district court's failure to make that and other *Graham* findings as evidence that *Graham* was not in fact applied."). In doing so, the Federal Circuit noted that a district court's failure to make a specific or correct finding on the level of skill in the art is only reversible if it influenced the ultimate conclusion. *Id.* Once again, the proper course of action is for Trutek to cross-examine Dr. Amiji on this issue at trial and whether his opinions change when applying the Court's definition of a POSA.

C. Dr. Amiji's Opinions Are Based on the Proper Legal Standards and Establish Genuine Issues of Material Fact Precluding Summary Judgment

Each of Dr. Amiji's opinions related to patent invalidity are supported by relevant factual and technical analysis. Further, Dr. Amiji reached his opinions by applying the proper interpretation of the applicable legal statutes under controlling Supreme Court and Federal Circuit law. Trutek does not credibly point to any of BlueWillow's invalidity defenses for which there are no genuine issues of material

fact regarding the validity of the '802 Patent. As such, Trutek is not entitled to summary judgment as a matter of law on any of BlueWillow's invalidity defenses.

a. Dr. Amiji's Opinions Regarding Section 101 Patent Ineligibility

Dr. Amiji did not misinterpret 35 U.S.C. § 101 or applicable law governing subject matter eligibility. Rather, it is Trutek who misapplies the law, both in terms of what is required by the statute and how that statute is interpreted in federal court.

As an initial matter, despite the fact that federal courts may take notice of the MPEP, it is well settled that USPTO guidelines and the MPEP are not binding on courts. *See Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002); *Hagenbuch v. Sonrai Sys.*, 130 F. Supp. 3d 1213, 1215 (N.D. Ill. 2015) ("the MPEP is not binding law"). Rather than acknowledge current binding Supreme Court law on the issue, Trutek instead continues to rely on USPTO guidance from the MPEP and old Supreme Court law (*Diamond v. Chakrabarty*). ECF 62 at 9.

For example, Trutek refers to a "first basic inquiry" (whether the claims are directed to a process or a composition of matter)[5] and a "second basic inquiry"

[5] Although Trutek complains that Dr. Amiji "misinterpreted the statute and law" because "he ignored the first basic inquiry" (ECF 62 at 8), this argument is of no moment. BlueWillow does not dispute that the asserted claims of the '802 patent are directed to a process and composition of matter. BlueWillow does disagree, however, that the asserted claims are directed to patentable subject matter when applying the Supreme Court's two step test articulated in *Alice*.

(whether the claims wholly embrace a judicial exception to patentability) governing subject matter eligibility. This framework is inconsistent with the subject matter eligibility framework currently set out by the Supreme Court and Federal Circuit.

35 U.S.C. § 101 provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor." But § 101 is not without limits. "Laws of nature and natural phenomena are not patentable, but applications and uses of such laws and phenomena may be patentable." *CareDX, Inc. v. Natera, Inc.*, 40 F.4th 1371, 1376 (Fed. Cir. 2022). "[A]dding conventional steps, specified at a high level of generality, to a law of nature or natural phenomenon does not make a claim to the law or phenomenon patentable." *Id*. (citations omitted).

More recently, the Supreme Court in *Alice* established a two-step framework for evaluating patent eligibility. Under step one, the court must determine whether the claims are directed to a patent-ineligible category, such as a natural phenomenon or law. *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 217-18 (2014). The inquiry asks whether the claims are "directed to a result or effect that itself is the [natural phenomenon/law] and merely invoke generic processes and machinery[,]" or whether the claims instead "focus on a specific means or method that improves the relevant technology." *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299, 1314 (Fed. Cir. 2016). "Where claims of a method patent are directed to an

application that starts and ends with a naturally occurring phenomenon, the patent fails to disclose patent eligible subject matter if the methods themselves are conventional, routine and well understood applications in the art." *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1378 (Fed. Cir. 2015). If a court finds the claims are "directed to" a natural phenomenon or law, it must proceed to step two, which is to assess whether the claims "contain[] an 'inventive concept' sufficient to 'transform' the claimed [natural phenomenon/law] into a patent-eligible application." *Alice*, 573 U.S. at 221. To be patent-eligible, such application "must provide something inventive, beyond mere 'well-understood, routine, conventional activity.'" *Genetic Techs., Ltd. v. Merial L.L.C.*, 818 F.3d 1369, at 1376 (Fed. Cir. 2016) (quoting *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 73 (2012)).

Trutek's Motion wholly ignores this binding Supreme Court and Federal Circuit precedent. In contrast, when reaching his opinions on patent eligibility, Dr. Amiji expressly applied these controlling legal standards. Ex. 1 at ¶¶ 42-43. For example, Dr. Amiji explained the asserted claims are directed to a law of nature or natural phenomena (i.e., step one), and why the asserted claims recite nothing more than well-understood, routine and conventional activity (i.e., step two):

> 202. The '802 Patent is directed to the effects of a law of nature or a natural phenomena, namely the principle that like charges repel each other, while unlike charges attract, e.g., a positive charge attracts

> a negative charge. While the Challenged Claims of the '802 patent recite additional elements, each of those additional claim elements are either conventional steps that are well known to a POSA or depend on the very same law of nature or natural phenomena.
>
> 205. . . . "[I]t is [] my opinion that each of the additional elements of the Challenged Claims recite nothing more than well-understood, routine and conventional activity or are directed to the very same law of nature or natural phenomena.
>
> 206. For example, a POSA would understand the desire to adjust "the adhesion of the thin film to permit said thin film to stick to the skin or tissue," and the '802 Patent specification and claims do not provide any further guidance as to how to do this or any unique method for doing so. Likewise, the claim element of "inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless" is also directed to well-understood, routine, and conventional activity. As explained above QACs were known to have antimicrobial properties since the 1930s, and BAC is likewise a well-known and commonly used disinfectant.
>
> 207. [E]ach of the additional claim limitations are provided at only a general level, as opposed to describing a specific application of the natural law/phenomena. For example, there is no mention in the '802 patent claims as to: (1) the specific charge density or other quantitative parameters that will be needed to create the electrostatic field; (2) what magnitude of electrostatic field is necessary to attract oppositely charged contaminants; (3) how far the electrostatic field needs to be from the application surface; (4) how much of the product must be applied to be effective; or (5) how long the composition must stay on the skin to be effective. In other words, the '802 patent claims simply rely on the general presence of the electrostatic field/natural phenomena to achieve the claimed result and function.

Ex. 1 at ¶¶ 202, 205-206, 207.

While Trutek also argues that the perspective of the POSA is irrelevant (ECF 62 at 11), it cites no authority supporting that assertion other than the fact that the

POSA is not mentioned in the statute. Again, Trutek mischaracterizes the law. Indeed, federal courts have expressly relied on expert testimony as to the understanding of a POSA when considering patent eligibility. *See Infernal Tech., LLC v. Sony Interactive Entertainment LLC,* No. 2:19-cv-00248-JRG, 2021 WL 405813, at *3 (E.D. Tex. Feb. 3, 2021) (permitting expert to testify as to "whether a person having ordinary skill in the art would understand the claim limitations, alone or in combination, to be routine, conventional, or well-understood").

Finally, while Trutek offers a number of reasons why the claims recite patent eligible subject matter (ECF 62 at 11), they are all unsupported attorney argument. Specifically, Trutek has not cited any evidence to contradict Dr. Amiji's opinions that the additional claim elements merely recite well-understood, routine, and conventional activity.[6] Even if Court accepts Trutek's position, it is clear from Dr. Amiji's testimony and opinions cited above that there are genuine issues of material fact and summary judgment of validity on this issue is inappropriate.

[6] In view of Dr. Amiji's unrebutted testimony on these points, BlueWillow respectfully submits that summary judgment in its favor finding the asserted claims to be directed to patent ineligible subject matter is appropriate.

b. Dr. Amiji's Opinions Regarding Lack of Credible Utility

For all of the reasons provided earlier, Dr. Amiji did not present "opinions of a legal nature" regarding lack of credible utility. Nor did Dr. Amiji "misinterpret" the patent statute or "create[] his own criteria" for determining credible utility. ECF 61 at 14. Indeed, it is Trutek who confuses the law regarding credible utility.

For example, the Federal Circuit has explained that the question of credible utility is one that is related to the concept of enablement under 35 U.S.C. § 112. *In re '318 Patent Infringement Litig.*, 583 F.3d 1317, 1323 (Fed. Cir. 2009) ("Enablement is closely related to the requirement for utility."). In addition, Trutek incorrectly argues that the perspective of the POSA is irrelevant and that test data and testing protocols are not required to establish utility. ECF 61 at 13.

On the first point, the question of whether the '802 patent satisfies the utility requirement is not whether it discloses any utility, as Plaintiff suggests, but rather, **whether a POSA would view the disclosed utility as credible**. *See In re '318 Patent Infringement Litigation*, 583 F.3d at 1327 (considering whether expert testimony demonstrated "that a person of ordinary skill in the art would have recognized that the specification conveyed the required assertion of a credible utility"). As to the second point, while testing may not *per se* be required in all circumstances, it is clear that a lack of testing and experimental data supporting the

claimed invention may lead to invalidity for lack of credible utility (and also for lack of enablement). Indeed, the Federal Circuit expressly considered the lack of any test results provided in the '318 patent specification when affirming the district court's finding of lack of enablement and utility, stating "the specification, even read in the light of the knowledge of those skilled in the art, does no more than state a hypothesis and propose testing to determine the accuracy of that hypothesis." *Id*. at 1324-25, 1327 (explaining that "[t]ypically, patent applications claiming new methods of treatment are supported by test results" and "in this case, however, neither in vitro test results nor animal tests results" were provided in the specification).

Trutek's Motion does not cite a single case applying 35 U.S.C. §§ 101 and/or 112 to determine whether a patent complies with the utility requirement, let alone any cases supporting its interpretation of the statute. In contrast, when reaching his opinions on lack of credible utility, Dr. Amiji applied the controlling Federal Circuit legal standards cited above. Ex. 1 at ¶ 45. Dr. Amiji's opinions on lack of credible utility fall squarely within this framework.

In addition, while Trutek asserts that the '802 patent specification "discloses ten different formulation embodiments" (ECF 62 at 13), Dr. Amiji explained why a POSA would not have recognized the specification to convey a credible utility based on that disclosure. More specifically, Dr. Amiji explains:

213. As an object of the claimed invention, the ’802 Patent states that “to accomplish the present invention, a formulation having at least one polyquaternary ammonium compound is prepared, such compounds, alone or together capable of creating an electrostatic field on and around a surface to which it is applied.” ’802 patent at 4:39-43.

214. A person skilled in the art reading the ’802 patent specification, however, would understand that while the ’802 patent does provide a laundry list of possible formulations, it does not include any data or test results for any of the formulations described, demonstrating to a person skilled in the art that there is a substantial likelihood that the claimed invention will work by “electrostatically attracting” particulate matter to a thin film applied to the nasal passages and holding the particulate matter in place through adhesion to the thin film in order to electrostatically inhibit such harmful particulate matter from infecting an individual. Nor does the ’802 patent even provide any discussion or suggestion of what types of tests or procedures could be employed by a person skilled in the art to determine whether such formulations would work as described and claimed. Finally, the ’802 patent also does not include any explanation or suggestion that the claimed invention is likely to work based on any similarities or analogies to other compositions or formulations that are known to work in a similar manner.

216. As such, in my opinion, apart from its reliance on the previous and well-known properties of cationic agents such as QACs and BAC, the ’802 Patent provides no other information to a person skilled in the art to support the assertion that the claimed invention also works by “electrostatically inhibiting” harmful particulate matter from infecting an individual. In other words, a person skilled in the art reading the ’802 Patent specification would understand that it does not provide anything other than a hypothesis that the claimed invention operates to “electrostatically inhibit” harmful particulate matter from infecting an individual.

Ex. 1 at ¶¶ 213-14, 216.

Dr. Amiji's opinion that the claims lack credible utility is based on well supported technical analysis of the underlying facts from the perspective of a POSA and he properly applied Federal Circuit law interpreting the statutory requirements. Nor does Trutek identify any factual element that is missing from Dr. Amiji's analysis. Dr. Amiji's opinions demonstrate the existence of genuine issues of fact with respect to utility, and summary judgment on this issue is inappropriate.

c. Dr. Amiji's Opinions Regarding Lack of Enablement and Written Description[7]

Once again, Trutek's assertion that Dr. Amiji does not fully understand the enablement and written description requirements (ECF 62 at 22) is premised on Trutek's own misunderstanding of the law. In both instances, Trutek relies on the statutory language, without full consideration of how the Federal Circuit has applied those statutory requirements. With respect to written description, Trutek does not even cite a single case explaining how the written description statutory requirement is applied by federal courts. And, contrary to Trutek's suggestion, the standard for

[7] Despite Plaintiff's recitation of both the AIA and pre-AIA versions of the patent statute, there is no confusion as to which version applies. Patents with effective filing dates "on or after" September 16, 2012 are governed by the AIA. *See Hologic, Inc. v. Smith & Nephew, Inc.*, 884 F.3d 1357, 1361 n.3 (Fed. Cir. 2018) (citing AIA § 4(e), 125 Stat. at 297). Thus, all patents with effective filing dates before September 12, 2012, are subject to pre-AIA law. Plaintiff agrees the '802 Patent is based upon a patent application filed in 2009. ECF 62 at 15. Thus, pre-AIA law applies.

written description is not merely the requirement "that the inventor provide a disclosure of his invention." ECF 62 at 16. Rather, the Federal Circuit has made clear that the statutory requirement of written description requires a disclosure that "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351, 1355-56 (Fed. Cir. 2010).

Likewise, with respect to enablement, while Trutek cites cases for the proposition that some experimentation is permitted as long as it is not undue, Trutek does not acknowledge any of the factors that the fact finder must consider when assessing whether the specification provides sufficient information to enable the POSA to make and use the claimed invention. More specifically, the "*Wands* factors" describe the factual inquiries underlying the enablement question: "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

When reaching his opinions on written description and enablement, Dr. Amiji applied the controlling Federal Circuit legal standards cited above. Ex. 1 at ¶¶ 46-50. In contrast, Trutek focuses on only one aspect of Dr. Amiji's opinions, which

are premised in part on the lack of testing in the '802 patent, and repeats the same argument that testing evidence is not required, without citing any supporting legal authority. ECF 62 at 16, 20.

As with utility, while test data may not *per se* be required under all circumstances, it is clear that the lack of test data or other experimental evidence supporting the claimed invention may render the claimed invention invalid for both lack of written description and enablement, particularly for method or functional claims. *Nuvo Pharms. (Ireland) Desig. Activity Co. v. Dr. Reddy's Labs. Inc.*, 923 F.3d 1368, 1377, 1381 (Fed. Cir. 2019) (finding claims invalid for lack of written description and rejecting argument that "experimental data and additional explanations demonstrating the invention works are unnecessary"); *Enzo Life Sciences, Inc. v. Roche Molecular Sys., Inc.*, 928 F.3d 1340, 1346-48 (Fed. Cir. 2019). Indeed, two of the *Wands* factors consider whether such testing is provided in the patent. *In re Wands*, 858 F.2d at 737 (the amount of direction or guidance in the specification and the presence or absence of working examples are both relevant to assessing enablement). Accordingly, the fact that Dr. Amiji's opinions are based, in part, on the lack of such testing, does not demonstrate any "misunderstanding" of the law on the part of Dr. Amiji.

Moreover, despite the implication otherwise, Dr. Amiji's opinions are not premised solely on the fact that the '802 patent specification provides no testing or

experimental data supporting the claimed invention. Likewise, while Trutek again points to the fact that the '802 patent specification discloses "ten separate embodiments showing formulations" that embody the claimed invention (ECF 62 at 17, 21), Dr. Amiji explained why those ten embodiments do not demonstrate to a POSA that the inventor was in possession of the claimed invention (written description), or enable a POSA to make and used the claimed invention without undue experimentation (enablement). Ex. 1 at ¶¶ 224-27, 231-35, 237-38.

Notably, the claimed invention is not simply directed to a formulation. Rather, the claimed invention is described in terms of the function it performs, i.e., a formulation and a method of using that formulation, wherein the formulation electrostatically inhibits harmful particulate matter from infecting an individual. Ex. 1 at ¶¶ 221-24, 232-34, 237-38; *see also Enzo Life Sciences*, 928 F.3d at 1346 (affirming district court's finding the patent was not enabled because while the specification disclosed how to create compounds with the correct structure, there was no guidance on which compounds would also have the correct function required by the claims); *Biogen Int'l GmbH v. Mylan Pharms. Inc.*, 18 F.4th 1333, 1343 (Fed. Cir. 2021) ("An inventor need not 'prove that a claimed pharmaceutical compound actually achieves a certain result. But when the inventor expressly claims that result, our case law provides that [such] result must be supported by adequate disclosure in the specification.'"); *Bial-Portela & CA. S.A. v. Alkem Labs. Ltd.*, No. 18-304-CFC-

CJB, 2022 WL 4244989, at *26 (D. Del. Sept. 14, 2022) (finding a lack of written description where there was no data in the specification to support the result claimed in the patent) (citing *Biogen*, 18 F.4th at 1343).

With respect to enablement, Dr. Amiji provided over seven pages of analysis addressing the: (1) nature of the invention and state of the prior art (*id*. Ex. 1 at ¶¶ 219-20); (2) breadth of the claims (*id*. at ¶¶ 221-23); (3) amount of direction or guidance in the specification and absence of working examples (*id*. at ¶¶ 224-28); (4) level of skill in the art and unpredictability in the art (*id*. at ¶¶ 229-30); and (5) the quantity of experimentation required (*id*. at ¶¶ 231-35). For example,

> 224. While the '802 Patent contains a large list of possible formulations and components that are purportedly within the scope of the claimed invention, the patent does not teach or disclose which combinations or percentages of the different components are necessary to provide the claimed functionality of "electrostatically inhibiting" harmful particulate matter from infecting an individual.
>
> 226. [T]he '802 Patent does not provide any examples that include the results of any testing of any of the disclosed formulations, let alone any guidance as to what types of tests should be conducted in order to determine whether a particular formulation would "operate in the manner" disclosed, e.g., by electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation. Nor does the '802 Patent provide any examples or any guidance as to how the percentages of components can be varied while still achieving "the same results."
>
> 227. Indeed, the '802 Patent even acknowledges that varying the percentages of the ingredients can affect the potency of the formulation and the consistency of the formulation. A person skill in the art would understand that both of these attributes could impact the ability of the

> formulation to "render said particulate material harmless" and the claimed adhesive and electrostatic properties of the formulation. The '802 Patent, however, does not provide any explanation or guidance as to how or to what degree "[v]arying the percentages for the active ingredients affects the potency of the formulation." Nor does the '802 Patent provide any explanation or guidance to how or to what degree "[v]arying the percentages for the inactive ingredients affects the consistency of the formulation."

Id. at ¶¶ 224-27.

Likewise, with respect to written description, Dr. Amiji explained why the lack of testing in the '802 patent specification does not reasonably convey to the POSA that the inventor was in possession of the invention:

> 237. While the '802 patent specification describes numerous formulations and different ranges of components that are purportedly within the scope of the claimed invention, the specification provides no data or testing of any kind demonstrating to a person of skilled in the art that the mere fact of applying a thin film having a positive charge will operate to "electrostatically attract" negatively charged particulate matter, adhering such particulate matter to the thin film, thereby inhibiting the particulate matter from infecting an individual. Nor does the '802 patent specification provide any indication to a person skilled in the art that the inventor even tested any of the formulations disclosed in the patent to assess whether they actually operate to electrostatically inhibit harmful particulate matter from infecting an individual through nasal inhalation. In other words, a person skilled in the art reading the '802 patent would understand that the inventor merely had a wish or hope that the claimed invention would operate in the manner described.
>
> 238. More specifically, the '802 Patent provides ten separate tables, each with many listed components and percent ranges, yet provides no data explaining which formulations will operate to electrostatically attract oppositely charged particulate matter. Nor is there any explanation or disclosure within the '802 Patent that would demonstrate to a person skilled in the art that the mere fact of

> electrostatically inhibiting such particulate matter will be sufficient to render such particulate matter harmless. Particularly in view of the countless formulations and variable components encompassed by the claims, the specification of the '802 Patent would not indicate to a POSA that the inventors possessed the claimed subject matter.

Id. at ¶¶ 237-38.

The remaining arguments presented by Trutek in its Motion have no bearing on the issue of whether summary judgment of patent validity is appropriate. For example, Trutek asserts that enablement "must be dealt with in two parts." ECF 62 at 18. With respect to the so-called "first part," Trutek explains that the claim language was amended during prosecution from "preventing" to "inhibiting," but fails to explain how this has any bearing on whether there is any absence of material fact related to patent validity such that summary judgment is appropriate. *Id*. at 19-20. Likewise, Trutek also asserts (solely by way of attorney argument without citation to any supporting evidence) that the asserted claims are enabled because the formulation provided in the tenth embodiment of the '802 patent "approximates the product first marketed by Plaintiff." *Id*. at 21 (citing Trutek's Markman presentation listing the tenth embodiment of the '802 patent). On this point, Dr. Amiji credibly explained why the bare assertion in the '802 patent that "[a]ll of the formulations described in TABLE 1-10 representing various embodiments of the Present Invention operate in the manner that was disclosed herein" would not demonstrate

possession of the claimed invention or enable a POSA to make and use the claimed invention without undue experimentation. Ex. 1 at ¶¶ 224-29, 232, 237-38.

Dr. Amiji's opinions that the asserted claims do not satisfy the written description and enablement requirements are based on adequately supported technical analysis of the underlying facts from the perspective of a POSA and properly apply Federal Circuit law interpreting the statutory requirements. Nor does Trutek identify any factual element that is missing from Dr. Amiji's analysis. Dr. Amiji's opinions demonstrate the existence of genuine issues of material fact with respect to written description and enablement and as such, summary judgment of validity on these issues is inappropriate.

d. Dr. Amiji's Opinions Regarding Anticipation and Obviousness in View of the Prior Art

Obviousness is a question of law based on underlying findings of fact. *In re Vaeck*, 947 F.2d 488, at 496 (Fed. Cir. 1991). "It is technological experience in the field of the invention that guides the determination of obviousness." *Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285, at 1297 (Fed. Cir. 2012). The relevant factual inquiries include the scope and content of the prior art, differences between the prior art and the claimed invention, and the level of ordinary skill in the art. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). Anticipation, and

the question of what a prior art reference discloses, are both questions of fact. *In re NTP*, 654 F.3d 1279, 1297 (Fed. Cir. 2011).

Dr. Amiji properly applied these legal principles when reaching his opinions on anticipation and obviousness. Ex. 1 at ¶¶ 32-35, 39-41. Dr. Amiji also addressed each of these factual inquiries at length when reaching his opinions regarding obviousness and anticipation. Dr. Amiji's opinions are supported by at least ten pages of technical analysis providing an overview of the asserted patent and the related technology area. *Id*. at ¶¶ 56-64, 69-80 (pages 23-26, 28-33). Likewise, Dr. Amiji's opinions directed to invalidity of the asserted claims in view of the prior art are supported by over sixty pages of analysis providing a technical overview of the prior art references and detailed analysis of why the disclosures and teachings of the prior art render the asserted claims anticipated and/or obvious. *Id*. at ¶¶ 82-107 (pages 33-44); 108-200 (pages 44-94). Dr. Amiji has ample technical and scientific experience in the field of the invention. Dr. Amiji correctly applied that experience when offering his opinions on what a POSA would have understood from the disclosure of the prior art. Despite Plaintiff's assertion to the contrary, the fact that Dr. Amiji may be a person of "extraordinary skill in the art" does not render his testimony inadmissible. *Kyocera*, 22 F.4th at 1377.

Trutek advances three additional complaints about Dr. Amiji's obviousness and anticipation opinions, each of which are without merit. First, Trutek confuses

applicable legal standards for whether the Rolf prior art reference must be enabling. For example, Trutek argues that a "reference that is not enabled cannot be used to anticipate a patent claim," yet concedes that "Dr. Amiji used this reference to show obviousness under 35 U.S.C. § 103." ECF 62 at 24. Nevertheless, Dr. Amiji responded to this argument, explaining how a POSA would understand the disclosure of Rolf to be enabled. *See* ECF 59-2 at PageID 1869-70 (addressing the fact that Rolf provides evidence of applying formulations containing essential oils to the skin, and the fact that a POSA would understand that the patch described in Rolf would operate according to the same principle as the claimed invention).

Second, Trutek mischaracterizes the law when asserting that "Dr. Amiji refers to single prior art references, thus invoking the anticipation standard." ECF 62 at 24-25. To the contrary, a single prior art reference can render a patent obvious if it would have been obvious to modify that reference to arrive at the claimed invention. *Game & Tech. Co. v. Activision Blizzard Inc.*, 926 F.3d 1370, 1381 (Fed. Cir. 2019); *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1361 (Fed. Cir. 2016).

Third, Trutek misstates the premise of BlueWillow's argument presented in its motion for summary judgment for anticipation based on Baker '476. ECF 62 at 26. While Trutek points to testimony from its expert, Mr. Haidri, asserting that the "HOLD" element is missing from Baker '476, Trutek does not address the fact that the "missing" element may be inherently present in the prior art. *Schering Corp. v.*

Geneva Pharms., Inc., 339 F.3d 1373, 1379 (Fed. Cir. 2003) (a missing claim element may be inherent and will anticipate if that inherent limitation "is the 'natural result flowing from' the explicit disclosure of the prior art"). Likewise, Trutek does not even acknowledge the remaining arguments presented by BlueWillow and Dr. Amiji explaining why the "HOLD" element is the "natural result" flowing from the use of the compositions disclosed in Baker '476. ECF 59 at 37-39; ECF 59-2 at PageID 1878-82.

For the foregoing reasons, Dr. Amiji did not misinterpret "the statutes and legal standards that deal with unpatentability based upon prior art" as asserted by Trutek. ECF 62 at 24. Dr. Amiji's opinions that the asserted claims are invalid for obviousness and/or anticipation in view of the prior art are based on adequately supported technical analysis of the underlying facts from the perspective of a POSA and properly apply Federal Circuit law interpreting the statutory requirements.

Moreover, while Trutek attempts to argue there is an issue with the factual basis for Dr. Amiji's opinions with respect to the Rolf and Baker '476 references, Trutek merely highlighted the difference of opinion between their expert, Haidri, and Dr. Amiji, for these two prior art references. And for one (Baker '476), BlueWillow respectfully submits that summary judgment is appropriate in favor of BlueWillow. ECF 59. Trutek raises no factual issue in connection with any of the remaining anticipation and obviousness defenses presented by BlueWillow based on

the other asserted prior art. ECF 62 at 23 (noting prior art defenses based on a number of other prior art references, including Wadstrom, Wahi '488, Baker '189, Khaled, Rabe, Katz and Wahi '790). At most, these differences in opinion only serve to highlight the existence of genuine issues of material fact with respect to obviousness and anticipation, thereby precluding summary judgment of validity.

V. CONCLUSION

For the reasons stated herein, Plaintiff's Motion for Partial Summary Judgment Declaring that U.S. Patent No. 8,163,802 is Valid should be denied in its entirety.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on June 5, 2023, I filed the foregoing document and this Certificate of Service with the Court using the ECF system.

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